EXHIBIT 54

EPA

FINAL DRAFT:

TECHNICAL SUPPORT DOCUMENT FOR A PROTOCOL TO ASSESS ASBESTOS-RELATED RISK

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A.4 SELECTION OF A "BEST ESTIMATE" OF K_L AND K_M

For each study for which a K_L or K_M is estimated, a "best estimate" is provided. For lung cancer, the best estimate of K_L (Table A-1) was generally assumed to be the maximum likelihood estimate (MLE) obtained with α estimated. For mesothelioma, the best estimate of K_M (Table A-2) is generally the maximum likelihood estimate derived from the best-fitting model in the form (Eq. A-3) for raw data and (Eq. A-4) for published data. As described in the descriptions of the individual studies, in a few cases these general rules had to be adapted to fit the particular form of the data available.

A.5 UNCERTAINTY IN K_L AND K_M

Statistical uncertainty in K_L and K_M estimates is expressed using 95% upper and lower statistical confidence limits. These limits (summarized in Table A-1 for lung cancer and Table A-2 for mesothelioma) were computed using the profile likelihood method and (for K_L) with α estimated.

However, non-statistical sources of uncertainty, such as model uncertainty and uncertainty in exposure, are also likely to be very important. Although these uncertainties are difficult to quantify, it is important to attempt quantification, since presentation of statistical uncertainty alone may provide a misleading picture of the reliability of the estimates. Consequently, an ad hoc approach to quantifying non-statistical uncertainty was adopted in this report. In this approach, the primary sources of uncertainty are identified. Then, for each study, a factor was selected for each uncertainty source using guidelines that will be described in this appendix. The individual factors were combined with the statistical confidence bounds to arrive at an "uncertainty range" for K_L or K_M for each particular cohort. These ranges are described in detail in following sections and are summarized in Table A-1 for lung cancer and Table A-2 for mesothelioma.

Because the most serious uncertainties among published epidemiology studies are often attributable to the estimation of exposure, three factors (F1, F2, and F3) were defined to address distinct sources of uncertainty associated with exposure. Two additional factors (F4L and F4M) were defined to account for uncertainty due to special limitations that had to be addressed to facilitate estimation of exposure-response factors from specific studies for lung cancer and mesothelioma, respectively.

To define the factors we used to address uncertainty associated with exposure, we first considered that, ideally, cumulative exposure would be estimated in an epidemiology study by:

- continuously monitoring the concentrations to which the worker is exposed over their entire working life;
- measuring such concentrations using personal monitors (samplers worn by workers with sampling ports placed within a few inches of the breathing zone of the worker); and